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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,913	02/05/2004	Steven W. Dow	86715.0002	5237

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,913	DOW ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-31, and 57-65, drawn to methods of eliciting an immunogen specific immune response in a mammal having cancer, comprising administering a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is a tumor antigen, and a composition comprising a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is a tumor antigen.

II. Claims 2-21, 32-43, and 57-65, drawn to methods of eliciting an immunogen specific immune response in a mammal having an infectious disease, comprising administering a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is an infectious disease antigen, and a composition comprising a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is an infectious disease antigen.

III. Claims 2-21, 44-49, 57-65, drawn to methods of eliciting an immunogen specific immune response in a mammal having disease associated with allergic inflammation, comprising administering a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is an allergen, and a composition comprising a liposome delivery vehicle and a recombinant nucleic acid molecule encoding an immunogen which is an allergen.

IV. Claims 50-53, drawn to methods of eliciting a tumor antigen specific immune

response comprising administering a liposome delivery vehicle and total RNA isolated from a tumor sample.

V. Claims 54-55, drawn to methods of eliciting a pathogen antigen specific immune response comprising administering a liposome delivery vehicle and total RNA isolated from an infectious disease pathogen.

Claims 1 and 56 link(s) inventions I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 56. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-III are directed to related methods and compositions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each invention is directed to eliciting an antigen specific immune response to materially different antigens in mammals suffering from materially different diseases. Cancer, disease caused by infectious pathogens, and allergic inflammation are unrelated diseases with unrelated etiologies and symptoms. Further, tumor antigens, derived from tumors, antigens from infectious disease pathogens, and allergens are non-overlapping groups of proteins derived from different types of organisms with no common structure or function. As such, each type of antigen cannot be used to treat a different type of disease. Thus, the search for each invention is not extensive and it would place an undue burden on the examiner to search and examine all three inventions together.

Inventions I-III and inventions IV-V are patentably distinct in that the methods of invention I-III utilize nucleic acids encoding antigens which are operatively linked to transcription control sequences whereas the nucleic acids of inventions IV-V are total RNA which has already been transcribed. As such, the physical, structural, and functional properties of the nucleic acids of inventions I-III and IV-V are materially different such that a search for RNA encoding tumor antigens or pathogen antigens is not coextensive with that for DNA or cDNA encoding tumor antigens or pathogen antigens. It is also noted that the nucleic acids of invention III encode allergens which are unrelated to the tumor antigens and pathogen antigens of

inventions IV-V. Therefore, it would place an undue burden on the examiner to search and examine all inventions together.

Invention IV-V are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each invention is directed to eliciting an antigen specific immune response to materially different antigens in mammals suffering from materially different diseases. Cancer and disease caused by infectious pathogens are unrelated diseases with unrelated etiologies and symptoms. Further, tumor antigens, derived from tumors and antigens from infectious disease pathogens are non-overlapping groups of proteins derived from different types of organisms with no common structure or function. As such, a tumor antigen cannot be used to treat a infectious pathogen and vice versa. Thus, the search for each invention is not extensive and it would place an undue burden on the examiner to search and examine both inventions together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of "cytokines":

a) hematopoietic growth factors

b) interleukins

c) interferons

d) tumor necrosis factors

e) immunoglobulin superfamily molecules

f) chemokines.

The species are independent or distinct because each species comprises proteins with materially different chemical, structural, and functional properties. Thus, the search for one species is not coextensive with any of the others such that it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7, 11-65 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains further contains claims directed to the following patentably distinct species of "tumor antigens from a cancer" of inventions I and IV where the cancer is:

a) melanoma

b) squamous cell carcinoma

c) breast cancer

d) head and neck cancer

e) thyroid cancer

f) soft tissue carcinoma

g)bone sarcoma

h) testicular cancer

i) prostatic cancer

j) ovarian cancer

k) bladder cancer

l) skin cancer

m) pancreatic cancer

n) hematopoietic neoplasias

o) gastrointestinal cancer

p) renal cell carcinoma

q) hepatic cancer

r) lung cancer

s) brain cancer

t) angiosarcomas

u) hemangiosarcoma

v) mast cell tumors

The species are independent or distinct because each species comprises tumor antigens derived from materially different types of tumor cells. Thus, the search for one species is not coextensive with any of the others such that it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26, 28-31, 50-53 and 56-65 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains further contains claims directed to the following patentably distinct species of "infectious disease antigens from a infectious pathogen" of inventions II and V where the pathogen is:

a) HIV

b) FIV

c) Mycobacterium tuberculosis

d) herpesvirus

e) papillomavirus

f) Candida

g) a parasite

The species are independent or distinct because each species comprises antigens derived from materially different infectious pathogens. Thus, the search for one species is not coextensive with any of the others such that it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-21, 32-35, 37-38, and 54-65 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains further contains claims directed to the following patentably distinct species of "allergens" of invention III:

a) plant pollens

b) drugs

c) foods

d) venoms

e)insect excretions

f)molds

g) animal fluids

h) animal hair

i) animal dander

The species are independent or distinct because each species comprises allergens derived from materially different organisms and further comprise materially different proteins. Thus, the search for one species is not coextensive with any of the others such that it would place an undue burden on the examiner to search and examine all species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-21, 44-45, 48-49, and 56-65 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note

that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER